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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,140	11/05/2001	Lyn Hughes	A01317	1934

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EXAMINER	
LUDLOW, JAN M	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 07/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	Examiner	Art Unit	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 6, 8 and 10 are objected to because of the following informalities: In claim 6, "the release medium" lacks antecedence. In claim 8, "said solid particles" lacks antecedence. In claim 10, "a" should precede "release medium" because "release medium" has not been previously recited. Appropriate correction is required.

2. Claims 5, 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 5, "can be continuously passed" is an unclear structural limitation because it is directed to intended use—is a means for continuously passing intended? In claim 8, "small" is a relative term, lacking comparative basis—how small is small? Further, how does the size of the particles in the sample limit the apparatus?

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 4-5, 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al.

7. Li teaches a cell 22, a supply of solvent circulating through detector 24, one-way valve 28 and line 26 into chamber 22, through filter 8 and out through chamber 12 and port 11 (col. 8, lines 47-60). Multiple sampling permits generation of a dissolution profile (abstract). Port 7 can be used to introduce the material to be tested (col. 6, line 10). The filter and pistons function as a mixer (col. 6, line 58). The particles may be transferred out of cell 22 into chamber 27 by piston 20.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Li as applied to claims 4-5, 7-10 above.

9. Li teaches that conventionally, dissolution cells are held at a constant temperature (col. 1, lines 50-55).

10. Li fails to explicitly teach that the inventive cell has a temperature control means.

11. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the cell of Li with a temperature controller in order to perform dissolution at a constant temperature as was known in the art as taught by Li.

12. Claims 4-5, 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Cosgrove.

13. Cosgrove teaches a cell 12, a supply of solvent 166, 168, a filter 50 for filtering samples before passage to detector 176, and agitator 28. Drain 208, 210 is used to remove medium from the cell, and is structurally capable of removing undissolved, small solids. Sampling may be continuous (col. 15, line 21). While Cosgrove does not explicitly teach passing solvent continuously into the cell, the pumps and controller are structurally capable of performing the intended use of claim 5.

14. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cosgrove as applied to claims 4-5, 7-10 above and further in view of Li.

15. Li teaches that conventionally, dissolution cells are held at a constant temperature (col. 1, lines 50-55).

16. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the cell of Cosgrove with a temperature controller in order to perform dissolution at a constant temperature as was known in the art as taught by Li.

17. Applicant's arguments filed July 25, 2003 have been fully considered but they are not persuasive.

Applicant argues that Li does not teach removing a sample such that undissolved solids are not included in the sample. This is not persuasive because Li teaches a filter 8 which "prevents undissolved compound from passing" into the portion of the chamber from which the sample is removed (col. 4, lines 30-38). Applicant further argues that "[o]perating a test of Li's invention will not give the results of the present invention," but the instant claims are directed to an apparatus, not a method, and therefore differences in the method of operation are not seen as germane to the instant claims. Applicant has pointed to no claim limitations reciting structural differences defining over the invention of Li. Note that the claims previously indicated as allowable were method claims, whereas applicant has elected to prosecute the broadened apparatus claims submitted with the amendment of July 25, 2003.

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

19. Smolen is cited in Cosgrove.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

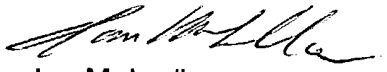
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is

filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (571) 272-1260. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jan M. Ludlow
Primary Examiner
Art Unit 1743

JML
July 7, 2004